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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,940	04/14/2005	Hardev Singh	PG4597USw	7146

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EXAMINER

KUNEMUND, ROBERT M

ART UNIT	PAPER NUMBER
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1722

MAIL DATE	DELIVERY MODE
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08/01/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/501,940

Applicant(s)

SINGH, HARDEV

Examiner

Robert M. Kunemund

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1722

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,3 and 16-26 is/are allowed.
- 6) ☒ Claim(s) 2, 4-15 27 and 28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

Claims 2 and 5 to 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al (5,471,001).

The Anderson et al reference teaches a method and apparatus for crystallization, note entire reference. The apparatus consists of a means to feed the material to be crystallized in to the crystallization chamber. There is a means in the chamber to create an ultrasonic pulse to aid in crystallization, note figure 1. There are outlet means to recover the crystals, note figures. The difference between the instant claims and the prior art is the inlet piping, reservoirs and controls. However, in the absence of unexpected results, it would have been obvious to one of ordinary skill in the art to determine through routine experimentation the optimum, operable feed means and controls in the Anderson et al reference in order to allow for proper mixing prior to the solution being affected by the ultrasonic device and to regulate the flow of materials in the and out of the chamber.

Claims 4 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al (5,471,001) in view of Al-Ghazawi et al (2003/0203937).

The Anderson et al reference is relied on for the same reasons as stated, supra, and differs from the instant claims in the use of an antisolvent and the materials crystallized. However, the Al-Ghazawi et al reference teaches crystallizing pharmaceutical compound by using solvent-antisolvent method, note page 4. It would have been obvious to one of ordinary skill in the art to modify the Anderson et al

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reference by the teachings of the Al-Ghazawi et al reference to use antisolvent solvent method and create crystals of pharmaceutical compounds in order to increase the uses of the apparatus. Further, the use of specific antisolvents with solvents and compounds would have been obvious to one of ordinary skill in the art in view of the prior art teachings as the prior art does teach different crystals require different solvent-antisolvent combinations.

Response to Applicants' Arguments

Applicant's arguments filed May 25, 2007 have been fully considered but they are not persuasive.

Applicants' argument concerning the Anderson et al reference is noted. However, it is well within the skill of the art to have more than one feed into a crystallizer. The claims are directed to an apparatus not a process. The material in the prior art must be capable of the process. It does not have to teach the process. IT would have been obvious to one of ordinary skill in the art to have two separate flow lines in order to increase control over the flow and crystallization conditions.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

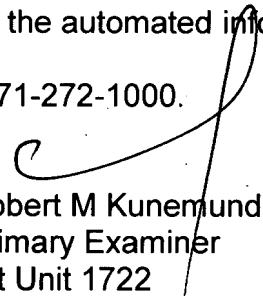
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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Kunemund whose telephone number is 571-272-1464. The examiner can normally be reached on 8 hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yogendra Gupta can be reached on 571-272-1316. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Robert M Kunemund
Primary Examiner
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